

REMARKS**Claim Amendment**

Claim 1 has been amended to recite the subject matter of Claims 7-9.

Claims 7-9 have been cancelled.

Claims 10-13 have been amended to correct their dependency.

Claim 21 has been amended to correct a self-evident error.

No new matter has been introduced by this amendment.

Claim Rejections under 35 U.S.C. §102(b)***Rejection of Claims 1-4, 7, and 28 over U.S. Pat. 4,904,261***

Claims 1-4, 7 and 28 are rejected as being anticipated by U.S. Pat. 4,904,261 (“Dove *et al.*”). The Examiner stated that FIGs. 1 and 2 of Dove *et al.* show an intervertebral implant formed as a banana-shaped unitary body with an exterior surface 15 and an interior surface 17 defining a recess. The Examiner also stated that Dove *et al.* teach front and back arcs 12 that have an equal radius of curvature, and that upper and lower edges 13, 14 form smoothly sloping surfaces since they are rounded holes.

Applicants have amended Claim 1 to recite the subject matter of Claims 7-9. Claims 8 and 9 are not rejected over Dove *et al.*. Claim 1, as amended, is novel in view of Dove *et al.* As presented by amended Claim 1, the present invention defines openings formed by bands of an interlinked mesh in a serpentine arrangement that are evenly spaced about a circumference of the unitary body. As seen from FIG. 7 (see also page 7, lines 14-15) and FIG. 16 (see also page 9, lines 1-2), cancellous bone material can be placed both in the interior recess of the unitary body and in the surrounding region, thus facilitating bone growth through the openings.

There is no discussion in Dove *et al.* of an intervertebral prosthesis defining openings that are evenly spaced about a circumference of the body of the prosthesis. Also, there is no discussion in Dove *et al.* of an intervertebral prosthesis wherein upper and lower edges of the prosthesis include bands that form a serpentine arrangement of an interlinked mesh. Therefore, Dove *et al.* do not disclose or suggest Applicants’ claimed invention as set forth in amended Claim 1.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-4 and 7-14 over U.S. Pat. 4,820,305

Claims 1-4 and 7-14 as being anticipated by U.S. Pat. 4,820,305 (“Harms *et al.*”). The Examiner stated that FIG. 1 of Harms shows an intervertebral implant formed as a unitary body with an exterior surface and an interior surface defining a recess of cylinder.

As described at on page 9, lines 14-21 of Applicants’ specification, the intervertebral prosthesis of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than previous systems at least in part because it is of unitary construction. The unitary body prosthesis of the present invention is easier to prepare and handle for a surgeon and will more reliably retain its shape and remain in the proper position once inserted than a device that is held together by screws, such as the prosthesis of Harms *et al.* As stated at page 9, lines 14-21 of Applicants’ specification:

An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use. The curvature of the cage of the invention mirrors the natural curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from either the anterior position or posterolateral position after standard discectomy. The implant of the invention can be manufactured from a variety of materials including both metals, metal alloys and synthetic, bioreabsorbable materials.

With reference to FIGs. 1 and 2, Harms *et al.* teach a cylindrical jacket of sheet material that is interconnected at two overlapping ends by a screw. As shown in FIGs. 4-7 (that include the “kidney” or “banana” shaped embodiment) the cylindrical jacket is rigidly connected with rings (elements 15 and 16) by screws (column 3, lines 1-3). Harms *et al.* do not disclose or suggest Applicants’ claimed invention as defined in the present Claims 1-4 and 7-14 because the device taught by Harms *et al.* includes several parts and is, therefore, not unitary.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections under 35 U.S.C. §103(a)

Claims 5, 6, 15-27 stand rejected under 35 U.S.C. §103(a) as being obvious variously in view of Dove *et al.*, Harms *et al.*, U.S. 6,302,914 (Michelson), U.S. 5,062,850 (McMillan *et al.*),

U.S. 6,245,108 (Biscup), U.S. 6,231,615 (Preissman) and U.S. 6,302,914 (McKay), either separately or in some combination. With respect to Claims 5 and 6, the Examiner stated that it would have been obvious in view of Dove *et al.* as a matter of design choice to modify the first radius of curvature to be less than the second radius of curvature. Regarding Claims 15-20, the Examiner stated that it would have been obvious to use alternative materials as taught by Dove *et al.* for the implant of Harms *et al.* As applied to Claims 24-26, the Examiner stated that it would have been obvious to use an implant with a width falling within the range of 24-28 mm, a height of about 10-16 mm and a length of about 10 mm, as taught by Michelson for the implant of Harms *et al.* With regard to Claim 21, the Examiner stated that it would have been obvious to use polyglycolic acid as the implant material as taught by MacMillan *et al.* for the vertebral implant of Harms *et al.* as modified by Dove *et al.* such that it degrades slowly to provide space for bone ingrowth. Concerning Claims 19 and 22, the Examiner stated that one skilled in the art would have considered it obvious to use the polymethylmethacrylate as the implant material as taught by Biscup for the vertebral implant of Harms *et al.* such that it is accepted by the patient's body and does not adversely cause irritation. The Examiner further stated that, regarding Claims 19, 22 and 23, it would be obvious to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Harms *et al.* such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement and antibiotic to a treatment site. With respect to Claim 27, the Examiner stated that it would have been obvious to use a thickness for the arc of the implant of "about 1.5 mm" as taught by McKay for the implant of Harms *et al.* as modified by Michelson such that it provides a durable support for the vertebrae that can withstand compressible loads.

None of the cited references, taken separately or in combination, remedy the deficiencies of Dove *et al.* or Harms *et al.* as applied to independent Claim 1, as amended. Specifically, none of the references, taken separately or in combination, disclose or suggest an intervertebral prosthesis that includes a banana-shaped unitary body defining openings that form a serpentine arrangement of an interlinking mesh, as in Applicants' claimed invention of amended Claim 1. Therefore, Applicants' invention is not obvious in view of the cited references, taken either separately or in combination, and meets the requirements of 35 U.S.C. §103(a).

Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Dated: 6/27/06